

THE PUBLIC'S HEALTH

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Ensuring Vaccine Safety



Vaccination is considered to be one of the most important public health interventions of the last century. With the continued emergence of bacterial and viral pathogens that are resistant to commonly used antibiotic

and antiviral agents, vaccines are poised to become even more important during the current century.¹ An expansion in the number of anticancer vaccines, as well as development of vaccines against debilitating neurological conditions, will further enhance the role of this important intervention.

A strong commitment to addressing concerns regarding vaccine safety during the long history of vaccine

development has led to the availability of safer and more effective vaccines. The transition from a smallpox vaccine that was propagated in pooled humanized lymph banks to one that was propagated in the skin of calves and sterilized with glycerine is one historical example of a change that improved vaccine safety.² The transition from whole cell pertussis vaccines to acellular pertussis vaccines currently in use is a modern day example.³

Vaccine Safety Standards

While high safety standards are set for all medicinal products, a higher level of safety is expected for vaccines because they are given to millions of healthy infants, children, adolescents, and adults every year to prevent disease.

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inSPOTLA Website Updated and Expanded

inSPOTLA <http://www.inspotla.org>, a pioneering STD/HIV partner notification website, has been updated and expanded. The website, launched in December 2005, allows individuals diagnosed with an STD or HIV to send an e-card (electronic postcard) to their partners notifying them that they may have been exposed. Originally tailored to men who have sex with men, the website has been revised and expanded to appeal to women and heterosexual men as well.

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313 North Figueroa Street, Room 806
Los Angeles, California 90012

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Medications are given to proportionately smaller numbers of people to treat illnesses. During the pre-licensure stage of development, vaccines, as well as other pharmaceutical products, undergo extensive safety and efficacy studies, initially using in-vitro laboratory systems, animal studies, and then, phased human trials. World-wide standardized case definitions for assessing adverse events, the use of data and safety monitoring boards, and the increased number of trial subjects, have all enhanced the effectiveness of vaccine pre-licensure studies in identifying problems at an early stage.⁴

Because rare and delayed vaccine reactions or reactions in subpopulations are usually only seen after hundreds of thousands of vaccine doses have been administered, post-licensure or post marketing studies are also very important. Such post-marketing studies that are undertaken by vaccine manufacturers and academic research centers are supplemented by the Vaccine Safety Data Link, a network of large health maintenance organizations where all patient outcomes over time are matched with immunization histories. Because the Vaccine Safety Data Link follows a very large number of vaccine recipients, it has proven to be especially valuable in assessing vaccine safety.⁴

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a post-licensure assessment system in which every health care provider should participate. VAERS was implemented jointly by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in 1990 in order to provide a unified national process for the reporting of specific post-vaccination events. The National Childhood Vaccine Injury Act of 1986 requires this reporting. Visit www.vaers.hhs.gov/pubs.htm or call VAERS at 800-822-7967 for a list of required reportable events. VAERS also provides a mechanism for reporting other clinically significant events occurring after vaccination whether or not they were suspected to be the result of vaccination.

Key Facts about VAERS

- VAERS is a passive reporting system that accepts reports from patients and their parents as well as health care providers.
- There is no restriction on the interval between vaccination and symptoms that can be reported.
- Suspected events should be reported on a preaddressed and postage-paid VAERS form. Online web-based reporting is also available by clicking on the VAERS web site: www.vaers.org.
- All immunization providers that receive vaccines through the Los Angeles County Department of Public Health Immunization Program (LACIP) should send their VAERS reports to LACIP. Reports will be reviewed by LACIP to identify immediate concerns that may need to be addressed. All reports are then forwarded to the national system.

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- Healthcare providers in this category can: a) fax their VAERS reports to 213-351-2782, attention Epidemiology and Surveillance or b) mail the reports to LACIP at 3530 Wilshire Boulevard, Suite 700, Los Angeles, CA, 90010-2340, attention: Epidemiology and Surveillance.

VAERS works!

VAERS has helped to ensure that the benefits of vaccines far outweigh the risks. Since 1990, VAERS has received over 123,000 reports, the majority of which describe mild side effects such as fever.⁵ Reporting has also identified several associations between significant events and vaccination, which in turn has prompted further investigation.

Recent VAERS Success Stories

- The identification of a rare but significant association between intussusception and the 1998 rotavirus vaccine, that led to an immediate halt to the vaccine's use and ultimately to its recall from the U.S. market in the fall of 1999.⁶
- The identification of a cluster of Guillain-Barre Syndrome (GBS) cases following vaccination with meningococcal conjugate vaccine (MCV4) in the summer of 2005. This led to several assessment studies that were inconclusive in determining the relationship between GBS and MCV4. Nevertheless, these studies prompted the CDC and the Advisory Committee on Immunization Practices to make "past history of GBS" a precaution when assessing a client's eligibility for receipt of MCV4.⁷

VAERS is a very important part of a comprehensive system that ensures vaccine safety. It is critical that all healthcare providers use it to report clinically significant events that occur after vaccination. For more information about VAERS, please visit the web site: www.vaers.org, or call 1-800-822-7967.

Resources

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Alvin Nelson El Amin, MD, MPH

Immunization Program

Los Angeles County Department of Public Health